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(54) Title: INTEGRATED MEDICAL INFORMATION MANAGEMENT SYSTEM

(54) Titre: SYSTEME DE GESTION INTEGREE DE L'INFORMATION MEDICALE

(57) Abstract

An integrated medical information management system includes at least one on-line central server and at least one remote access terminal. The at least one on-line central server contains patient related data for at least one patient. The at least one remote access terminal is used to interactively access the patient related data for the at least one patient from the at least one on-line central server to generate interactive reports based on the patient related data for the at least one patient on the at least one remote access terminal. Preferably, the at least one on-line central server is connected to the at least one remote access terminal through an Internet connection and utilizes an internet web browser to interactively access the at least one on-line central server.

(57) Abrégé

Cette invention concerne un système de gestion intégrée de l'information médicale comprenant au moins un serveur central en ligne et au moins un terminal d'accès à distance. Ce terminal permet d'accéder de manière interactive à des données médicales concernant au moins un patient à partir du serveur central en ligne dans le but de produire des rapports interactifs à partir des données médicales concernant au moins un patient sur le terminal d'accès. Le serveur central en ligne est de préférence relié au terminal d'accès via une connexion Internet et un navigateur Internet.

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(54) Title: INTEGRATED MEDICAL INFORMATION MANAGEMENT SYSTEM

(57) Abstract: An integrated medical information management system includes at least one on-line central server and at least one remote access terminal. The at least one on-line central server contains patient related data for at least one patient. The at least one remote access terminal is used to interactively access the patient related data for the at least one patient from the at least one on-line central server to generate interactive reports based on the patient related data for the at least one patient on the at least one remote access terminal. Preferably, the at least one on-line central server is connected to the at least one remote access terminal through an Internet connection and utilizes an internet web browser to interactively access the at least one on-line central server.

Description

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TITLE

Integrated Medical Information Management System

RELATED APPLICATIONS

This application claims priority on U.S. provisional patent application Serial No. 60/134,981, filed May 20, 1999 and entitled "Diabetes Integrated Management System" and U.S. Patent Application Serial No. 09/409,014 filed September 29, 1999 and entitled "Communication Station and Software for Interfacing with an Infusion Pump, Analyte Monitor, Analyte Meter, or the like (published as WO 00/18449 on April 6, 2000), which are specifically incorporated by reference herein.

FIELD OF THE INVENTION

This invention relates to an integrated medical information management system, and in particular embodiments, to an integrated system that utilizes remote communication stations, facsimile, E-mail and the internet to retrieve patient data and to provide reports to a patient, healthcare provider, HMO and/or insurer to manage diabetes.

BACKGROUND OF THE INVENTION

Currently, insulin must be provided to people with Type 1 and many with Type 2 diabetes (approximately 40% of patients with Type 2 diabetes use insulin). Traditionally, since it cannot be taken orally, insulin has been injected with a syringe. More recently, use of external infusion pump therapy has been increasing, especially for delivering insulin for diabetics using devices worn on a belt, in a pocket, or the like, with the insulin delivered via a catheter with a percutaneous needle or cannula placed in the subcutaneous tissue. For example, as of 1995, less than 5% of Type I diabetics in the United States were using pump therapy. There are now about 7% of the currently over 900,000 Type I diabetics in the U.S. using insulin pump therapy, and the percentage is now growing at a rate of over 2% each year. Moreover, the number of Type I diabetics is growing at 3% or more per year. In addition, growing numbers of insulin using Type II diabetics are using external insulin infusion pumps. Physicians have recognized

that continuous infusion provides greater control of a diabetic's condition, and are increasingly prescribing it for patients. Greater control reduces the complications associated with the disease of diabetes.

Traditionally, data from the treatment of diabetes is stored in logbook or is stored in the memory of a treatment or monitoring device. This information is then transferred by hand or downloaded to a local computer. However, the data is not easily transferred to the healthcare provider or specialist. The data must be brought to those who need to review it or it is transferred over a modem. Unfortunately, this normally requires a visit to the healthcare provider and the data must be reviewed at that time. It is generally not feasible for the data to be transmitted to the healthcare provider on a regular basis for routine monitoring and analysis, since the healthcare provider must analyze and interpret the data using their own time and computer.

SUMMARY OF THE DISCLOSURE

It is an object of an embodiment of the present invention to provide an integrated medical information management system, which obviates for practical purposes, the above-mentioned limitations.

According to an embodiment of the invention, an integrated medical information management system includes at least one on-line central server and at least one remote access terminal. The at least one on-line central server contains patient related data for at least one patient. The at least one remote access terminal is used to interactively access the patient related data for the at least one patient from the on-line central server to generate interactive reports based on the patient related data for the at least one patient on the at least one remote access terminal. Preferably, the at least one on-line central server is connected to the at least one remote access terminal through an internet connection and the at least one remote access terminal utilizes an internet web browser to interactively access the at least one on-line central server.

Preferred embodiments use patient related data that is related to the disease of diabetes. For instance, the patient related data may be medication infusion data, glucose monitor data and/or glucose meter data.

In another embodiment of the invention, an integrated medical information management system includes at least one on-line central server, at least one medical device, at least one data receiving device and at least one remote access device. The at least one on-line central server contains patient related data for at least one patient. The at least one medical device is related to treatment of a disease of a patient, and includes memory to store data about the use of the device by the patient. The at least one data receiving device receives the data from the at least one medical device, and uploads the data to the at least one on-line central server as patient related data. The at least one remote access device is for receiving patient related data from the at least one on-line central server. Preferably, the at least one least one remote access device is a remote access terminal used to interactively access the patient related data for the at least one patient to generate interactive reports based on the patient related data for the at least one patient on the at least one remote access terminal.

The at least one on-line central server is connected to the at least one remote access terminal through an internet or intranet connection and utilizes an internet web browser to interactively access the at least one on-line central server. Alternatively, the at least one remote access device is a facsimile machine. Additional embodiments further include a communication station interface between the at least one medical device and the at least one data receiving device. Preferred medical devices include infusion devices, glucose monitors and/or glucose meters.

Preferred embodiments use patient related data that is related to the disease of diabetes. For instance, the patient related data may be medication infusion data, glucose monitor data and/or glucose meter data.

In further embodiments, the at least one remote access device is used to receive E-mail reports. In addition, the at least one data receiving device is capable of receiving requests for reports from the at least one on-line central server. In other embodiments, the at least one data receiving device is capable of receiving requests for ordering supplies, and/or for scheduling appointments. Also, the at least one remote access device further includes an ability to order

supplies through the at least one on-line central server based on the uploaded data from the at least one medical device.

In particular embodiments, the system further includes a data bus that allows data from different types of the at least one medical device to be captured, stored, manipulated and reported on independent of the specific type of device connected to the data bus. Preferably, the data bus utilizes data elements and/or collections of data elements to process data.

In other embodiments, the at least one on-line central server automatically generates reports at predetermined times. The reports may be sent out by mail, E-mail, internet, intranet, dedicated lines, or the like. Further embodiments can create group reports of more than the at least one patient are generated. In addition, reports may be sent to managed care providers (HMOs). Embodiments may also include the ability to schedule appointments, to bill clients, and/or to process insurance claims.

In further embodiments, the data is captured automatically by a device and/or captured by manual entry of data by an individual. In particular embodiments, the data is glucose consumption data, exercise data, caloric burn data, medication consumption data from sources independent of infusion data, lab test data, or the like. In other embodiments, once data is received by the at least one remote access device, the patient can review the data, and may also be able to analyze it and generate reports. In still other embodiments, the data is used to generate reports. For instance, the data is used to produce reports that include components selected from the group of graphical elements, textual elements, numerical elements and tabular elements that represent the data. The data may be used to produce reports on the use of medical supplies and/or produce reports that provide conclusions regarding the use of medical supplies. In other embodiments, the data is used to produce reports that highlight problems or issues and/or produce reports that highlight or recommend areas for adjustments in regimes. The embodiments may also utilize expert logic.

In still further embodiments, the system generates reports independent of the type of at least one medical device, at least one data receiving device or at least one remote access device utilized by the system. For instance, the system

includes the capability to combine some to all of the data on the at least one on-line central server into a single data storage and reporting mechanism. Alternatively, the system includes the capability to combine or juxtapose some to all of the data on the at least one on-line central server into a single report. In other alternatives, the system includes the capability to form conclusions and recommend actions based on some to all of the data on the at least one on-line central server by correlating various portions of data in ways not otherwise be possible when referencing the various portions of data separately.

In another embodiment, a data storage and reporting system includes a data bus that allows data collected from various different medical devices, which use various different formats and types of data. In addition, the data bus allows the data to be collected and reported on in a manner independent of a health care provider, a patient, or a system being required to be aware of the difference between the different formats and types of data.

In additional embodiments, the data bus utilizes data elements and/or collections of data to process data. Also, the system that transforms the various data formats from the various different medical devices into a single consistent representation for storage.

In particular embodiments, the system allows mixed data from the different medical devices to be stored into a database in a single operation. The system may also transform the various data formats from the various different medical devices into a single consistent representation for reporting.

In other particular embodiments, the system allows data from the different medical devices to be stored and presented in a consistent style of presentation. Also, the system may also allow data from the different medical devices to be stored, manipulated, and reported on independent of developing program code to specifically handle each different medical device. In further embodiments, the system allows simultaneous calculations on data combined from different medical devices independent of the mix of different medical data devices from which the data originated. Also, the system may allow calculations on data combined from the different medical devices to be organized as different groups to be performed in a single operation. For instance, the system computes an average blood

glucose value as measured by several different blood glucose meters, for each day in a series of days with a single operation.

In additional embodiments, the system allows data from new different medical devices to be combined into the system with minimal of additional programming. Also, the system may allow data from different medical devices with similar purposes having data in various different data formats and types to be combined on a single, uniform report or graph. (For example, a single patient may use two different blood glucose meters from two different companies simultaneously. The system would allow the information from these meters to be combined (even interspersed) on a single report).

Other features and advantages of the invention will become apparent from the following detailed description, taken in conjunction with the accompanying drawings, which illustrate, by way of example, various features of embodiments of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

A detailed description of embodiments of the invention will be made with reference to the accompanying drawings, wherein like numerals designate corresponding parts in the several figures.

Fig. 1 is a system architecture drawing of the integrated medical information management system in accordance with an embodiment of the present invention.

Fig. 2 is a system architecture drawing of a prototype integrated medical information management system in accordance with another embodiment of the present invention.

Figs. 3-5 are block diagrams and drawings further illustrating the reporting architecture used by the integrated medical information management system shown in Fig. 1.

Fig. 6 is a block diagram and drawing showing how data is uploaded from infusion devices, monitors and meters to a PC, laptop or the internet through a user interface in accordance with an embodiment of the present invention.

Fig. 7 is a block diagram illustrating the structure of the data bus utilized in the integrated medical information management system.

Fig. 8 is a diagram of examples of data management applications for specific market segments.

Fig. 9 is a screen view of an interactive report generating screen used by a healthcare provider over the internet to obtain detailed reports.

Fig. 10 is a three day report generated in response to the report requested from the screen in Fig. 9.

Fig. 11 is an expanded view of the first day shown in Fig. 10.

Fig. 12 is an expanded view of the second day shown in Fig. 10.

Fig. 13 is an expanded view of the third day shown in Fig. 10.

Fig. 14 is a comparison view of the three days shown in Fig. 10 overlaid on the same graph to show how each day compared to the others.

Fig. 15 is a two week summary chart report, with glucose monitor data, modal day, blood glucose summary statistics and insulin usage reports.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

As shown in the drawings for purposes of illustration, the invention is embodied in an integrated medical information management system for assisting patients, healthcare providers, Managed care or Health Maintenance Organizations (HMOs), and insurers in managing the information available from medical treatment to better treat the symptoms and effects of the disease. Preferred embodiments are directed to the management of diabetes information and utilize infusion devices and glucose monitors and/or meters that have the ability to store information about the infusion of fluids and the measured glucose levels. In further embodiments, patients, or local healthcare providers, download stored data from the devices using a Communication-Station I or II, modem, or the like, to a PC, laptop, or data processor, and then to a central server either via a modem, E-mail or internet connection. The stored data is then analyzed and preliminary reports are provided to the patient's physician or other healthcare provider by facsimile, E-mail or internet. If desired or required, the physician can also access the data on the server through an internet (or modem) connection to

generate custom reports to highlight or further analyze the data regarding the patient. In additional embodiments, healthcare providers, HMOs and insurers can access the stored data (generally in a database) to obtain general patient statistics and to receive warnings about individual patients that appear to be outside of the normal disease state condition, and which may require attention from a healthcare provider. In alternative embodiments, the data may also be downloaded to the healthcare provider for additional detailed analysis on a PC, laptop, or processor that is locally based with the healthcare provider. Preferred embodiments are directed to managing the disease of diabetes. However, alternative embodiments may be directed to other diseases, such as asthma, heart disease, AIDS, cancer, or the like.

The integrated medical information management system provides centralized storage and processing for patients, healthcare providers, HMOs and providers. The patient uses infusion devices, such as an infusion pump, or the like, to administer medication. The infusion device includes memory to store the infusion history data, as well as any alarms or other relevant data needed for proper infusion. During infusion, the patient will also monitor their condition using a glucose meter with individual finger pricks and/or a glucose monitor for continuous (or near continuous) monitoring of the patients condition. These devices also store the data and relevant information about the patient's condition.

Generally, every few days the patient will place the infusion device, the meter and/or monitor into a Communication-Station I or II, or other suitable device, to download data to a local PC, laptop computer, data processor, or the like. In alternative embodiments, different intervals, such as other day multiples, weeks, or months may be used. In other alternative embodiments, the infusion device, monitor and/or meter may include the ability to transmit the data directly to the PC, laptop computer, data processor, or the like. After downloading the data, the patient may view and work with the data for their own review. As discussed, the integrated medical information management system will generally work in conjunction with the Communication Station ("Com-Station"), which is described in U.S. Patent Application Serial No. 09/409,014 filed September 29, 1999 and entitled "Communication Station and Software for Interfacing with an

Infusion Pump, Analyte Monitor, Analyte Meter, or the like (published as WO 00/18449 on April 6, 2000), which is incorporated by reference herein, to upload stored data from insulin pumps, blood glucose meters ("Meters"), and continuous glucose monitors ("Monitors") to a central server for analysis and storage. At the most basic level of service, the server will analyze the uploaded data and fax a report consisting of several pages of graphical and tabular information to the health care provider's office in advance of or during a patient visit.

In other embodiments, more sophisticated options for report configuration and delivery will be available via an Internet interface. In additional embodiments, the data will be uploaded to a central server, either by modem connection or through the Internet. Alternatively, the data may be uploaded directly through the Communication-Station. In further alternatives, the data may be uploaded to the central server through a satellite link, cellular telephone link, E-mail, or the like. In still further alternative embodiments, the uploaded data may be interpreted and used to automatically order supplies and materials to be sent to the patient to maintain the patients condition.

Once the data is uploaded to the central server, a report will be periodically generated and sent to the healthcare provider. In some embodiments, the report is facsimiled. However, alternative embodiments may E-mail the report and/or send downloaded raw data for the healthcare provider to review and study. If a healthcare provider desires more detailed analysis or a special report, the healthcare provider can order through E-mail and/or go on-line to request a custom report for particular periods, parameters, comparisons, or the like. The connection may be through the internet, modem or other suitable data transfer method, and the data for each of the healthcare provider's patients can be accessed and then reported on. Thus, the healthcare provider is able to quickly interact with the data and obtain desired reports. The physician may also instruct the central server to monitor particular aspects or parameters of the patient's data and to trigger an alert or notification upon the occurrence of a particular event or condition. This allows the healthcare provider to learn about various disease conditions on a more frequent basis. In addition, the healthcare provider can obtain detailed data that can be reviewed prior to the patient coming in for a visit,

which tends to make the visit much more productive and useful to both the patient and the healthcare provider.

HMOs and/or insurers can also benefit from the central database, since they can monitor statistical information regarding all patients on the central server, and can monitor their patient subscribers as a group to determine key aspects of the disease that affect their subscribers. It could also provide them with alerts when particular patients (or classes of patients) appear to be having difficulties so that proactive treatment can be ordered.

In preferred embodiments, patients will be identified by the serial numbers of their devices. Some form of authentication security will be required to ensure that the identity of a particular device/patient cannot be confused or obtained without authorization. Any data transmitted over a public network or the internet may be encrypted for added security. In addition, all internet transactions will be encrypted, and internet based access will be protected by username/password login.

Fig. 1 illustrates the system architecture of an integrated medical information management system 10 in accordance with an embodiment of the present invention. Preferred embodiments utilize an analysis server 12 that accesses a patient database 14 used to store and analyze data as described in more detail below. Patient data in the database 14 is generally stored for specified periods of time (such as 3 months, a year, or the like) and older data will then be stored in off-line media. The analysis server 12 is also connected to various external data sources and processors through data modems 16, fax modems 18, and/or a web server 20 that connects to the internet 22. In alternative embodiments, the various servers may be combined or formed as a plurality of different interconnected servers with the configuration being dependent on the system architecture, the number of anticipated users, the type of connections used, the amount of data handled, or the like.

In particular embodiments, a patient home computer 24 can connect to the web server 20 through the internet 22. However, in alternative embodiments, the patient home computer 24 may connect to the analysis server 12 through the data modems 16 (using dedicated dial-in lines or local access numbers connected to

third party networks for access), a direct wire connection, or the like. Preferably, a Dr.'s office computer 26 is connected to the analysis server 12 through the data modems 16. However, in alternative embodiments, the Dr.'s office computer 26 may be connected to the web server 20 through the internet 22.

Although only shown for the Dr.'s office computer 26, the following may also be connected to the patient home computer 24. In preferred embodiments, the Dr.'s office computer 26 is connected to a communication station 28 that can download data from a glucose monitor 30 (such as those produced by MiniMed Inc. for continuous or near continuous glucose measurements) and/or an infusion device 32 (such as the MiniMed 407C infusion pump, 507C infusion pump, 508 infusion pump, or the like). In alternative embodiments, the Dr.'s office computer 26 may be omitted and the glucose monitor 30 and infusion device 32 are connected to a communication station II 34, which includes additional capabilities such as a display, additional control buttons, RF communication capabilities and built in modems. A detailed description of a communication station and communication station II is disclosed in U.S. Patent No. 5,376,070 and U.S. Patent Application Serial No. 09/409,014 filed September 29, 1999 and entitled "Communication Station and Software for Interfacing with an Infusion Pump, Analyte Monitor, Analyte Meter, or the like (published as WO 00/18449 on April 6, 2000), which are herein incorporated by reference in their entirety. The Dr.'s office computer 26 may also be capable of being connected to other devices, such as glucose meters 36 (such as the AccuChek by Roche, the Lifescan by Johnson & Johnson, the Medisense meter by Abbott, the Elite by Bayer, or the like) through a direct wire, IR, RF connection, or the like. In alternative embodiments, the glucose meters 36 may be connected through the communication station 28 or communication station II 34 in either a pass-through mode or using the stations 28 or 34 as an interface. In particular embodiments, the receiving device for reports and data, and the remote access device for providing and receiving data may be the same device.

The integrated medical information management system 10 also may include managed care organization computers (HMO) 38 that are connected to the web server 20 through the internet 22 or, alternatively, to the analysis server 12

through the data modems 16. There may be other computers 40, such as laptops, accounting computers, research computers, or the like, attached to the web server 20 thought the internet, a dedicated link, or alternatively, to the analysis server 12 though the data modems 16, or the like. Other data transmitting/receiving appliances 42, such as fax machines, scanners (not shown), or the like, may be connected to the analysis server 12 through the fax modems 18 to send and receive data for analysis. Alternative embodiments may utilize software on computers to communicate with the analysis server 12 by other methods, such as IR data links, satellite data links, cellular data links, or the like.

Fig. 2 is a system architecture drawing of an integrated medical information management system 100 in accordance with another embodiment of the present invention. The integrated medical information management system 100 is similar to the integrated medical information management system 10, but is designed to work with intranet 102 connections rather than the internet connections. This system is suitable for management within an organization with satellite offices. This system may also provide greater security, where this is a concern, since the public internet is not used for data transmissions. Preferred embodiments utilize an analysis server 104 that accesses a patient data base 106. The data base 106 is used to store and analyze data as described in more detail below. The analysis server 104 is also connected to various external data sources and processors through data modems 108, fax modems 110, and/or connects to the intranet 102. Preferably, a Dr.'s office computer 112 (or alternatively, a patient home computer) is connected to the analysis server 104 through the data modems 108. However, in alternative embodiments, the Dr.'s office computer 112 may be connected through the intranet 102. In preferred embodiments, the Dr.'s office computer 112 is connected to a communication station 114 that can download data from a glucose monitor 116 (such as those produced by MiniMed Inc. for continuous or near continuous glucose measurements) and/or an infusion device 118 (such as the MiniMed 407C infusion pump, 507C infusion pump, 508 infusion pump, or the like). A detailed description of a communication station is disclosed in U.S. Patent No. 5,376,070 and U.S. Patent Application Serial No. 09/409,014 filed September 29, 1999 and entitled "Communication Station and

Software for Interfacing with an Infusion Pump, Analyte Monitor, Analyte Meter, or the like (published as WO 00/18449 on April 6, 2000), which are herein incorporated by reference in their entirety. Further alternatives may use a communication station II as discussed above. The Dr.'s office computer 112 is also capable of being connected to other devices, such as glucose meters 120 (such as the AccuChek by Roche, the Lifescan by Johnson & Johnson, the Medisense meter by Abbott, the Elite by Bayer, or the like) through a direct wire, IR, RF connection, or the like. In alternative embodiments, the glucose meters 120 may be connected through the communication station 114 in either a pass-through mode or using the station 114 as an interface.

The integrated medical information management system 100 also may include managed care organization computers (HMO) 122 that are connected through the intranet 102 or, alternatively, to the analysis server 104 through the data modems 108. There may be other computers, such as laptops, accounting computers, research computers, or the like, attached to the intranet, or alternatively, to the analysis server 104 though the data modems 108. Other data transmitting/receiving appliances 124, such as fax machines, scanners (not shown), or the like, may be connected to the analysis server 104 through the fax modems 110 to send and receive data for analysis. Alternative embodiments may utilize software on computers to communicate with the analysis server 104 by other methods, such as IR data links, satellite data links, cellular data links, or the like.

Figs. 3-5 are block diagrams that illustrate the reporting architecture 200 used by the integrated medical information management systems shown in Figs. 1 and 2. The reporting architecture 200 receives data through a receiving program 202 that manages communication with the communication-stations I or II, computers, medical devices, or the like. The receiving program 202 stores the data in an intermediate format (which may be a disk file 206). The data is then processed by a loading program 204, which is responsible for storing the information to the system database 212. The loading program 204 uses the same data bus 208 (discussed in more detail below) for manipulating and storing data, as is used by the rest of the reporting architecture and applications. This data bus

208 stores and retrieves data from the database using a database access framework 210 that includes a database object model 214 and a database interface 216. The database access framework 210 and/or data bus 208 support additional administrative and customer service applications 218, including, but are not limited to, client and physician account establishment, customer service support, client billing, or the like.

Reporting applications 220 are used to generate various reports for use by the health care provider, patient, HMO, administrator, or the like. The reporting applications 220 include a report scheduler 222 to schedule when reports are to be generated and sent out. The reporting applications 220 also include report specifier logic 224 that specifies the logic and parameters used to generate by means of templates. A report layout module 226 and report imaging module 228 are used to generate the actual the reports. In addition, a charting module 230 and chart imaging module 232 are used to generate graphs used in a report. In the current embodiment, reports are generated in multiple formats or combinations of formats including HTML, GIF, Encapsulated PostScript, PostScript, PDF and TIFF. In alternative embodiments, other formats such as JPEG, MPEG, or the like, may be used. In addition, the reporting applications 220 also include an exception and expert logic module 234 to identify and communicate abnormal or unusual conditions based on the report data, and to make recommendations accordingly.

The output of the reporting applications 220 may be sent to the report delivery queues 236 for delivery by fax or E-mail. The fax delivery mechanism 238 has faxing software and image generation software to deliver reports and charts via facsimile transmission to various receiving device. The E-mail delivery mechanism 240 sends out reports via E-mail, such as text messages, attached files, embedded graphics, a combination of the preceding, or the like. In addition, reports may be generated in HTML section 242 and published on a protected web site for viewing with a web browser. A disk file 244 may be used to manage the report delivery queues and the HTML web-based generation of reports. In alternative embodiments, the reports may be printed out and then sent out by mail, Federal Express, UPS, or the like. In still further alternative

embodiments, requests for reports may be received by mail, E-mail, telephone requests, telephone requests to the server, or the like.

Fig. 6 is a block diagram and drawing showing an application 300 for collecting data directly from medical devices including infusion devices 302, monitors 304, meters 306 and 308, and other medical devices 310 and uploading the data to a central server through a PC (such as 24 and 26 described above). This application 300 consists of a user interface that utilizes a data bus 312 (described below) to communicate to a device/data manager 314. The device/data manager 314 uses a plug in software architecture to communicate with the various medical devices. These plug-in modules may communicate directly with a serial port interface 316, or may use a library module 318 and/or 320 to communicate with the medical devices directly. The serial port interface 316 is connectable to a communication station 322 (as described above) to connect the infusion devices 302 and/or the monitors 304, and/or meter devices 306 that utilize a pass-through in the communication station 322. In other embodiments, the serial port interface 316 is connectable to meters 306 that have the capability to directly connect to a serial data port. The application 300 includes a file transfer module 324 for transferring data files through a modem 326.

Thus, embodiments of the system allow for data to be collected from various different medical devices, which use various different formats and types of data. The health care provider, or the patient, is not required to be aware of the difference between these different medical devices. The system transforms the various data formats into a single consistent representation for storage and reporting. This provides the ability for data from multiple devices to be stored and presented consistently, and allows data from new devices to be combined into the system with a minimum of additional development work. For example, patient A uses a blood glucose meter manufactured by company 1. Patient B uses a blood glucose meter manufactured by company 2. Both patients see physician C who is able to view a report for each patient without having to be aware of the differences between the blood glucose meters from companies 1 and 2. Therefore, embodiments of the system allow data from devices with similar

purposes but different data formats and types to be combined on a single, uniform report. For example, a single patient may use two different blood glucose meters from two different companies simultaneously. The system would allow the data from these meters to be combined (even interspersed) on a single report. The same capability would apply to other medical devices, such as infusion devices, glucose monitors, or the like.

Further embodiments will use software that performs the download of information from the devices using a "plug-in" architecture to allow rapid development of drivers for additional devices (e.g. insulin pens with memory, smart pill boxes, other blood glucose meters, etc.). This provides adaptability with consideration given to future products.

Fig. 8 is a diagram of examples of data management applications for specific market segments.

Figs. 9-15 illustrate exemplary views of reports and screens that may be generated by the integrated medical information management system. Generally, all of the screens shown in Figs. 9-15 are part of a single report; however, other embodiments may provide each screen separately, omit some or add additional screens, as an individual report. Fig. 9 is a screen view of an interactive report generating screen used by a healthcare provider over the internet to obtain detailed reports. Fig. 10 is a three day report generated in response to the report requested from the screen in Fig. 9. Fig. 11 is an expanded view of the first day shown in Fig. 10. Fig. 12 is an expanded view of the second day shown in Fig. 10. Fig. 13 is an expanded view of the third day shown in Fig. 10. Fig. 14 is a comparison view of the three days shown in Fig. 10 overlaid on the same graph to show how each day compared to the other days. Fig. 15 is a two week summary chart report, with glucose monitor data, modal day, blood glucose summary statistics and insulin usage reports. Other reports may be prepared and utilized by the integrated medical information management system, such as those disclosed and described in U.S. Patent Application Serial No. 09/409,014 filed September 29, 1999 and entitled "Communication Station and Software for Interfacing with an Infusion Pump, Analyte Monitor, Analyte Meter, or the like (published as WO 00/18449 on April 6, 2000), which is herein incorporated by reference.

For instance, data from a device sensing a patient's physiological condition can be combined with data concerning medication usage. The system then generates reports that juxtapose, in either graphical or textual format, the physiological and medication delivery data, glucose levels, carbohydrate consumption, or the like. The system may also incorporate expert system logic for generating reports or identifying patients with problems to aid the health care provider in identifying unusual conditions or behavior based on the availability of both the physiological sensing data and the medication data in the same report.

The reporting architecture will operate generally by extracting information from the device data stored in the database based on specified criteria, performing calculations, creating charts (i.e. graphs, pie, bar or column charts, hybrids, or the like), and generating reports. The basic report is generally one to several pages and includes graphical and tabular display of data, summary statistics, and exceptions. In further embodiments, the reports may include recommendations, compliance ratings, or the like. In preferred embodiments, the system will provide a flexible reporting structure which will allow new reports to be created relatively easily, will use configurable rule based logic for drawing conclusions and making recommendations, and will allow for smarter devices with increased memory capacity.

In general, reports will consist of a set of components laid-out as blocks on a page. The reporting system will use report templates to specify the layout of the reports. These templates will be written in a standard layout or markup language. The template language and layout processor must be rich enough to allow arbitrary arrangement of report components on a page, and support the variety of output format described herein. Report components will generally consist of charts, tables, or text blocks. Elements may be mixed within a report component by using sub-components. This will allow reports to be hierarchical in design and will enable multiple reports to reuse a single component. Report components may mix data from different devices or types of devices. The report layout mechanism will support text flow, line breaks, or the like. Text components may use a variety of fonts, sizes, and styles. (HTML based reports

created for viewing on the internet will have some limitations in this area due to the nature of Internet browsers.)

The charting system will create charts in a variety of formats including bar and stacked bar, line, scatter, and area charts, and any combination of these. The charting system will support flexible chart axis configuration including multiple axes for overlaid data. Most charts will use some form of date or time scale for the X-axis, and this scale may range from hours to years. In other embodiments, the charting system will support color charts where appropriate. Chart components may be generated as images using a document format separate from the report template language.

In preferred embodiments, the integrated medical information management system will deliver reports under several selectable scenarios/conditions: prior to a care provider appointment; regularly (such as monthly or quarterly (potentially also to Managed care (HMOs)); when a health risk exception is detected (e.g. prolonged high or low blood sugar, or the like). Generally, the system will provide a 2-3 page report that will be faxed to the care provider's office. In this embodiment, no computer will be required either for the patient or care provider. Further embodiments provide reports on demand to support diagnosis of control problems, maintaining control during illness, or the like. Still other embodiments will provide reports on a daily basis during initiation of pump therapy; each time data is uploaded to the integrated medical information management system, or the like.

In further embodiments, the user of the integrated medical information management system uses the system to obtain treatment options by internet, E-mail, facsimile, or the like. The system may also provide patient and physician education via interactive tutorials on the internet and proactive notifications with tips and education guidance by E-mail, facsimile, or the like. These can include disease state management and patient population risk management.

Online ordering of patient supplies, medication, devices, and accessories including reorder notification may also be available. Along with this, the integrated medical information management system may provide online product support for products ordered or used by users of the integrated medical

information management system, such as frequently asked questions, instruction manuals, training aids (including interactive and non-interactive aids), programming tips, user suggestions, or the like. Still further embodiments may provide access to disease specific online patient community groups including posting, reading and replying to messages.

Healthcare provider users of the integrated medical information management system will generally receive individual patient data management and recommendations. However, further embodiments may also provide overall practice quality management including patient exam and outcome measurements (HbA1c tests, eye exams, etc.), and compliance with quality metrics and published standards of care. Other embodiments may include comparisons with other patient population on a patient-by-patient and total practice basis. Managed Care (HMO) users of the integrated medical information management system will generally receive disease state management services. In additional embodiments, Managed Care (HMO) users will be provided with support for identification and management of high risk patients.

Preferred embodiments of the present invention use the integrated medical information management system to provide a more complete patient record; for automated collection and analysis of the patient record; for more accurate and immediate evaluation of patient health and compliance with a health care regimen; for more frequent interaction with the care provider; for providing information rather than data that is more summarized than the raw data, such as graphically versus tabular, or the like. Other embodiments provide additional data collection based on automated patient surveys to support both direct patient care and medical and market research, such as by online surveys, market research, or the like. Still further embodiments provide home monitoring services to provide alarms and call for assistance should unusual or pre-selected conditions be determined by the devices used by the user. Additional embodiments may include a carbohydrate counter and meal planner to assist the user in evaluating the amount of carbohydrates to consume and the effects on insulin delivery requirements.

As described above, the integrated medical information management system will use one ore more servers to connect to the internet and/or to the intranet to produce a web site. The web site of the integrated medical information management system will integrate the services and allow access to the services under a single login with simple, intuitive navigation. For instance, once users are connected to the web site, the users can enter additional data such as meals and exercise; configure reports; produce ad hoc reports as web pages as often as desired: configure periodic shipment of diabetes supplies by care providers or patients (within policy limits etc.); order additional supplies on demand for reasons such as: extra supplies for trips, lost or damaged supplies, change in consumption, change in meters, or the like. Supplies can also include ancillary items such as syringes, tape, ketone test sticks, or the like. Further embodiments may permit users to order pump accessories and other merchandise.

As described above, internet based training may be used with the integrated medical information management system. Typical training modules include, but are not limited to: a diabetes primer; basic insulin pump operation; advanced insulin pump operation; operation of other devices; carbohydrate counting; problem troubleshooting; avoiding hypoglycemia; sick day guidelines; infusion site management. In preferred embodiments, the carbohydrate calculator would include a large database of common food items, a meal planner, and ability to transfer calculations easily to patient records in the medical information management system and connected medical device.

In particular embodiments, the integrated medical information management system utilizes E-mail messages that are sent to notify or remind patients of various items. Typical preprogrammed Emails could include items such as: notification to upload device data; notification of an upcoming care provider appointment / reminder to schedule appointment; notification to order supplies / check inventory; clinical or technical service bulletins; customer satisfaction surveys, or the like. The timing and specific content of these email messages will be configurable by either the patient, the health care provider, the managed care (HMOs) provider, all of the above, or the like. In additional embodiments, the service will offer a general reminder facility that can be used to

send arbitrary reminder email messages related to diabetes care. Both care providers and patients may configure the service to provide reminders. The system may also be configured to generate (or suggest) automatic reminders based on uploaded data (e.g. remind the patient to test 3:00 AM blood glucose 2 times per week).

In further embodiments, a user uses a continuous glucose monitor to monitor a patient for hypoglycemic condition, and action is taken when such a condition is detected. The glucose monitor receiving device would be connected to a communication device (such as that shown in U.S. Patent application Serial No. 09/377,472 filed August 19, 1999 and entitled "Telemetered Characteristic Monitor System and Method of Using the Same (published as PCT publication WO 00/18449) which is herein incorporated by reference) which would monitor the glucose level and initiate communication with the integrated medical information management system if a preset level is reached. The integrated medical information management system would then take a selected action such as notifying a family member, health care provider, or emergency services.

In particular embodiments, upon request, a data file uploaded from a patient's infusion device or other device will be transmitted to a clinical services department to assist in diagnosing potential product or configuration problems. The ability for clinical services to interrogate an infusion device pump remotely in real time may be an option.

In its most basic form, all patient interaction with the integrated medical information management system takes place through the upload procedure only, and all care provider interaction (for patient establishment and report template configuration) takes place via the telephone (IVR or live agent) (i.e. no computer will be required). In addition, a secure internet interface will be provided for care providers with Internet access.

Data transmission will employ a flexible and robust protocol that will integrate data from multiple types of devices and can be extended to new devices and data types. This protocol will isolate all but the lowest layers of software from the details of the specific devices. This protocol will incorporate a data

format that is suitable for storage in files. Such files could be stored for archival purposes, sent via email for store-and-forward transmission of data, etc.

Fig. 7 is a block diagram illustrating the structure of a data bus 400 utilized in embodiments of the integrated medical information management system. The data bus includes data elements 402 that includes various data values 410, as well as date and time 404, and other information (such as data type 406, device information 408), or the like. The data elements 402 may be linked together as collections 416 of data elements. The data bus 400 may also include collections of data elements 412 with groupings of data elements, which aggregate related data elements (such as data elements 402) together in various forms. The collections of data elements 412 can include data elements 402, and collection information 414 that link the collection of data elements 412 together, or the like. The data bus 400 also includes a database interface 418 for interfacing with a database, as described above. Use of these data bus elements permits a user to connect different devices independent of a detailed knowledge of the data structure for each device.

Three design goals of the data bus 400 are as follows:

Natural	This term refers to the idea that a programmer can write code easily without undue complexity or regular reference to documentation. To a programmer familiar with the system, the resulting code should be readable almost like English.
Transparent	This term refers to the idea that data can be manipulated without regard to the specific values or organization of the data itself, or of its origin. High level operations are supported without complex control structures. This is best accomplished by encapsulating as many details as possible in lower layers of the architecture.
General	This term refers to the idea that a function or structure is designed with the broadest possible problem definition in mind. This characteristic will allow the system to be applied to new data sources and applications with little or no change.

In preferred embodiments, the data bus 400 is implemented as a collection of classes (i.e. object definitions), which are used internally by the integrated medical information management system and other software applications for collection, transmission, storage, analysis, and reporting of data. In preferred embodiments, only the lowest layers of device communication modules will

perform any device specific processing. Generally, some of the reporting functions will require device specific knowledge, but this dependency will be kept to a minimum, and data from multiple devices will be able to be combined transparently. Programmers using the data bus are able to save combinations of different types of data from one or more devices into the database with a simple, one line operation. No special formatting or conversion will be required. Data may also be retrieved from the database transparently based on a variety of criteria such as device type (infusion device, monitor, meter, or the like) or date/time range.

The data bus 400 is designed to make data manipulation easy and as independent of device specific constraints as possible. The basic intent is to give programmers a powerful set of tools to allow them to work with the data to produce complex reports by writing a small amount of natural code. For example, the programmer can express a computation such as: "find all blood glucose readings over the last week and compute the average values by time buckets across a generic (modal) day" with just a few lines of code. This computation is complex in that it encapsulates a parameterized database retrieval, a transformation to convert date/time stamps to time stamps only, a collection of data into buckets, and multiple averaging computations. The data bus 400 will also integrate closely with the report layout and rendering subsystems such that these systems will share a common language, object definitions, and data structures.

In preferred embodiments, the data bus data structures contain the report data along with the source data in a structure that closely mirrors the actual report. These data structures and the Application Programming Interface provided to access the data structure will allow the report generation mechanism to interact with the data structure in a very simple manner to extract the data for the report.

In preferred embodiments, individual data elements 402 represent the data on the data bus 400 as a fundamental unit of device or other data. In their simplest form, the data elements 402 consist of a date/time stamp, and a value, and they are associated with a particular physical device and a particular patient.

Individual data elements are typically utilized with the data bus as

follows:

a) created by a device object as part of an upload operation. Data elements 402 from the same upload operation are associated together in a data set;

b) transmitted via modem from the remote data collection location to the system where the software applications are running;

c) stored in the database;

d) retrieved with criteria corresponding to a specific report component;

e) organized and analyzed by report logic. New data elements 402 or collections of data elements 412 may be created by the results of computations or transformations; and

f) output onto a report via a report generation mechanism, which traverses the data structure created by the report logic.

In preferred embodiments, collections of data elements 412 serve two purposes: a) represent a collection of data elements 402 that have been collected or summarized based on some criteria (collection of data elements 412 can be used as containers to create arbitrary hierarchies of data); and b) represent a computation or transformation on a data elements 402 or set of data elements 402.

In preferred embodiments, the following steps generally describe to flow of data along the data bus:

Collection - An object representing a specific device type communicates with a device to upload the device's information, and then creates a collection of data elements 402 representing the uploaded information, along with other information about the device and upload operation.

Transmission - A set of these collections are uploaded from a remote computer or other device to a server where the Applications are running.

Storage - A program on the server collects the transferred information and stores it in the database.

Data retrieval - The reporting application determines the

appropriate report to generate. Based on the type of report, the application extracts data from the database as one or more collection of data elements 402.

Data Analysis - Reports are made up of individual report components organized hierarchically (some components may perform their own data retrieval operations). Report components can be broken down into two basic types: charts and numerical/tabular information. Preferably, each component uses data bus elements and custom logic to organize the report data as appropriate for the report, and to perform computations on the data. The results of these computations are stored in the report data structure. In general, the report data structures closely mirror the structure of the report itself.

Report generation - Beginning at the top of the hierarchy, each report component is instructed to generate its sub-report. The report generation is accomplished using templates for each report component. In general, because the data structures mirror the reports themselves, the instructions for extracting information from the data structure for tabular reports can be embedded in the component template itself without additional computation or logic. Charts are more complex, and thus each chart generally requires some amount of specific data manipulation and chart formatting logic.

While the description above refers to particular embodiments of the present invention, it will be understood that many modifications may be made without departing from the spirit thereof. The accompanying claims are intended to cover such modifications as would fall within the true scope and spirit of the present invention.

The presently disclosed embodiments are therefore to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims, rather than the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.

Claims

WHAT IS CLAIMED IS:

1. An integrated medical information management system, the system comprising:

at least one on-line central server containing patient related data for at least one patient; and

at least one remote access terminal to interactively access the patient related data for the at least one patient to generate interactive reports based on the patient related data for the at least one patient on the at least one remote access terminal.

2. The system according to claim 1, wherein the at least one on-line central server is connected to the at least one remote access terminal through an internet connection.

3. The system according to claim 2, wherein the at least one remote access terminal utilizes an internet web browser to interactively access the at least one on-line central server.

4. The system according to claim 1, wherein the patient related data is data related to the disease of diabetes.

5. The system according to claim 4, wherein the patient related data is medication infusion data.

6. The system according to claim 4, wherein the patient related data is glucose monitor data.

7. The system according to claim 4, wherein the patient related data is glucose meter data.

8. An integrated medical information management system, the system comprising:

at least one on-line central server containing patient related data for at least one patient;

at least one medical device related to treatment of a disease of a patient, wherein the at least one medical device includes memory to store data about the device;

at least one data receiving device for receiving the data from the at least one medical device, wherein the at least one data receiving device uploads the data to the at least one on-line central server as patient related data; and

at least one remote access device for receiving patient related data from the on-line central server.

9. The system according to claim 8, wherein the at least one remote access device is a remote access terminal used to interactively access the patient related data for the at least one patient to generate interactive reports based on the patient related data for the at least one patient on the at least one remote access terminal.

10. The system according to claim 8, wherein the at least one on-line central server is connected to the at least one remote access device through an internet connection.

11. The system according to claim 10, wherein the at least one remote access device utilizes an internet web browser to interactively access the at least one on-line central server.

12. The system according to claim 8, wherein the patient related data is data related to the disease of diabetes.

13. The system according to claim 12, wherein the patient related data is medication infusion data.

14. The system according to claim 12, wherein the patient related data is glucose monitor data.

15. The system according to claim 12, wherein the patient related data is glucose meter data.

16. The system according to claim 8, wherein the at least one remote access device is a facsimile machine.

17. The system according to claim 8, wherein the at least one medical device is an infusion device.

18. The system according to claim 8, wherein the at least one medical device is a glucose monitor.

19. The system according to claim 8, wherein the at least one medical device is a glucose meter.

20. The system according to claim 8, wherein the at least one remote access device is used to receive E-mail reports.

21. The system according to claim 8, wherein the at least one data receiving device is capable of receiving E-mail requests for reports from the at least one on-line central server.

22. The system according to claim 8, wherein the at least one data receiving device is capable of receiving requests for ordering supplies.

23. The system according to claim 8, wherein the at least one data receiving device is capable of receiving requests for scheduling appointments.

24. The system according to claim 8, further including a data bus that allows different types of the at least one medical device to access the at least one data receiving device independent of configuration programming by the at least one patient.

25. The system according to claim 8, wherein the at least one remote access device further includes an ability to order supplies through the at least one on-line central server based on the uploaded data from the at least one medical device.

26. The system according to claim 8, further including a communication station interface between the at least one medical device and the at least one data receiving device.

27. The system according to claim 8, wherein the at least one on-line central server automatically generates reports at predetermined times.

28. The system according to claim 8, wherein reports are sent out by mail.

29. The system according to claim 8, wherein group reports of more than the at least one patient are generated.

30. The system according to claim 8, wherein reports are sent to managed care providers (HMOs).

31. The system according to claim 8, wherein the at least one on-line central server is connected to the at least one remote access device through an intranet connection.

32. The system according to claim 8, further including the ability to schedule appointments.

33. The system according to claim 8, further including the ability to bill clients.

34. The system according to claim 8, further including the ability to process insurance claims.

35. The system according to claim 8, wherein the data is glucose consumption data.

36. The system according to claim 8, wherein the data is captured automatically by the at least one medical device.

37. The system according to claim 8, wherein the data is inputted manually by the patient.

38. The system according to claim 8, wherein the data is exercise data.

39. The system according to claim 8, wherein the data is caloric burn data.

40. The system according to claim 8, wherein the data is medication consumption data from sources independent of infusion data.

41. The system according to claim 8, wherein the data is lab test data.

42. The system according to claim 8, wherein once data is received by the at least one remote access device, the patient can review the data.

43. The system according to claim 8, wherein the data is used to generate reports.

44. The system according to claim 8, wherein the data is used to produce reports that include components selected from the group of graphical elements, textual elements, numerical elements and tabular elements that represent the data.

45. The system according to claim 8, wherein the data is used to produce reports on the use of medical supplies.

46. The system according to claim 8, wherein the data is used to produce reports that provide conclusions regarding the use of medical supplies.

47. The system according to claim 8, wherein the data is used to produce reports that highlight problems, issues or identify and make adjustments.

48. The system according to claim 47, wherein the system uses expert logic to highlight problems or issues.

49. The system according to claim 8, wherein the data is used to produce reports that highlight or recommend areas for adjustments in therapy regimes.

50. The system according to claim 8, wherein the data is used to produce reports that highlight or recommend areas for adjustments in lifestyle.

51. The system according to claim 8, wherein the system generates reports utilizing a same report format independent of the type of at least one medical device, at least one data receiving device or at least one remote access device utilized by the system.

52. The system according to claim 8, wherein the system includes the capability to combine some to all of the data on the at least one on-line central server into a single data storage and reporting mechanism.

53. The system according to claim 8, wherein the system includes the capability to combine or juxtapose some to all of the data on the at least one on-line central server into a single report.

54. The system according to claim 8, wherein the system includes the capability to form conclusions and recommend actions based on some to all of the data on the at least one on-line central server by correlating various portions of data in ways not otherwise be possible when referencing the various portions of data separately.

55. A data storage and reporting system comprising:

a data bus that allows data collected from various different medical devices which use various different formats and types of data, wherein the data bus allows the data to be collected and reported on in a manner independent of a health care provider, a patient, or a system being required to be aware of the difference between the different formats and types of data.

56. The system according to claim 55, wherein the system that transforms the various data formats from the various different medical devices into a single consistent representation for storage.

57. The system according to claim 55, wherein the system allows mixed data from the different medical devices to be stored into a database in a single operation.

58. The system according to claim 55, wherein the system transforms the various data formats from the various different medical devices into a single consistent representation for reporting.

59. The system according to claim 55, wherein the system allows data from the different medical devices to be stored and presented in a consistent style of presentation.

60. The system according to claim 55, wherein the system allows data from the different medical devices to be stored, manipulated, and reported on independent of developing program code to specifically handle each different medical device.

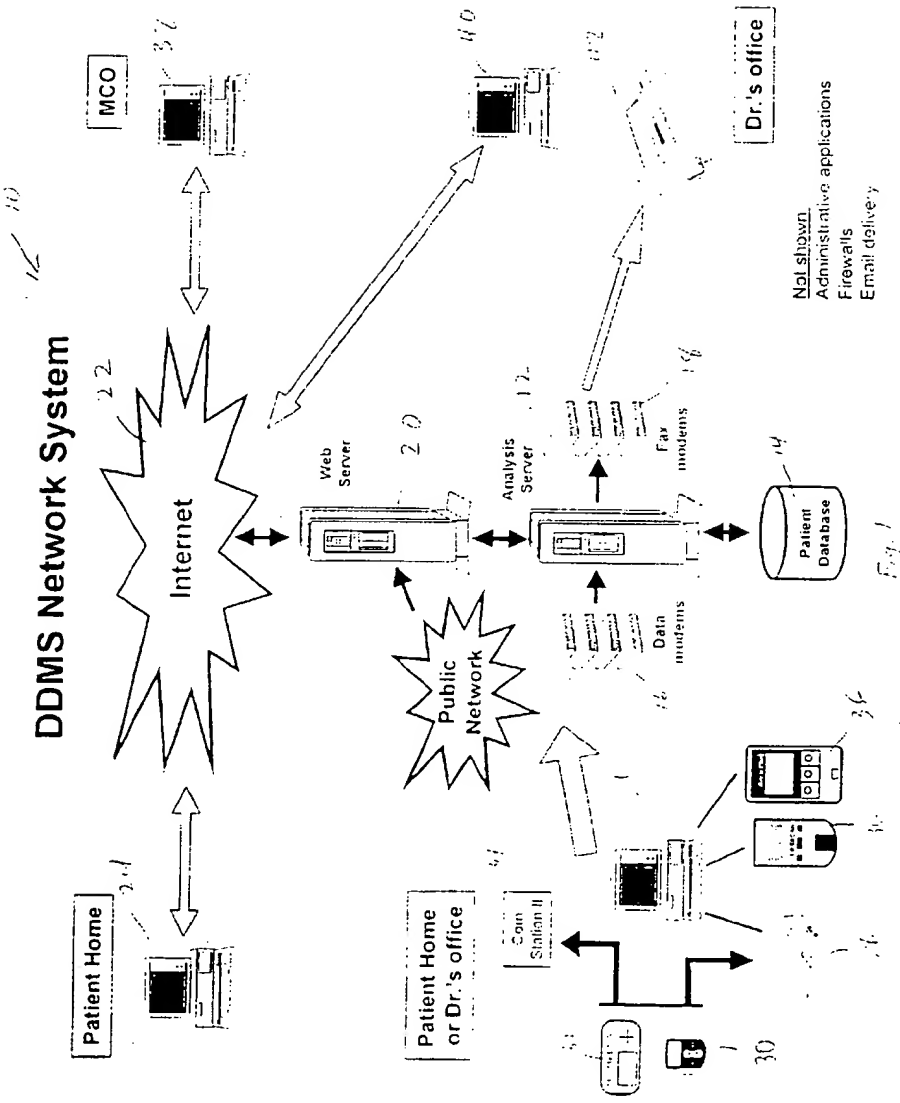
61. The system according to claim 55, wherein the system allows simultaneous calculations on data combined from different medical devices independent of the mix of different medical data devices from which the data originated.

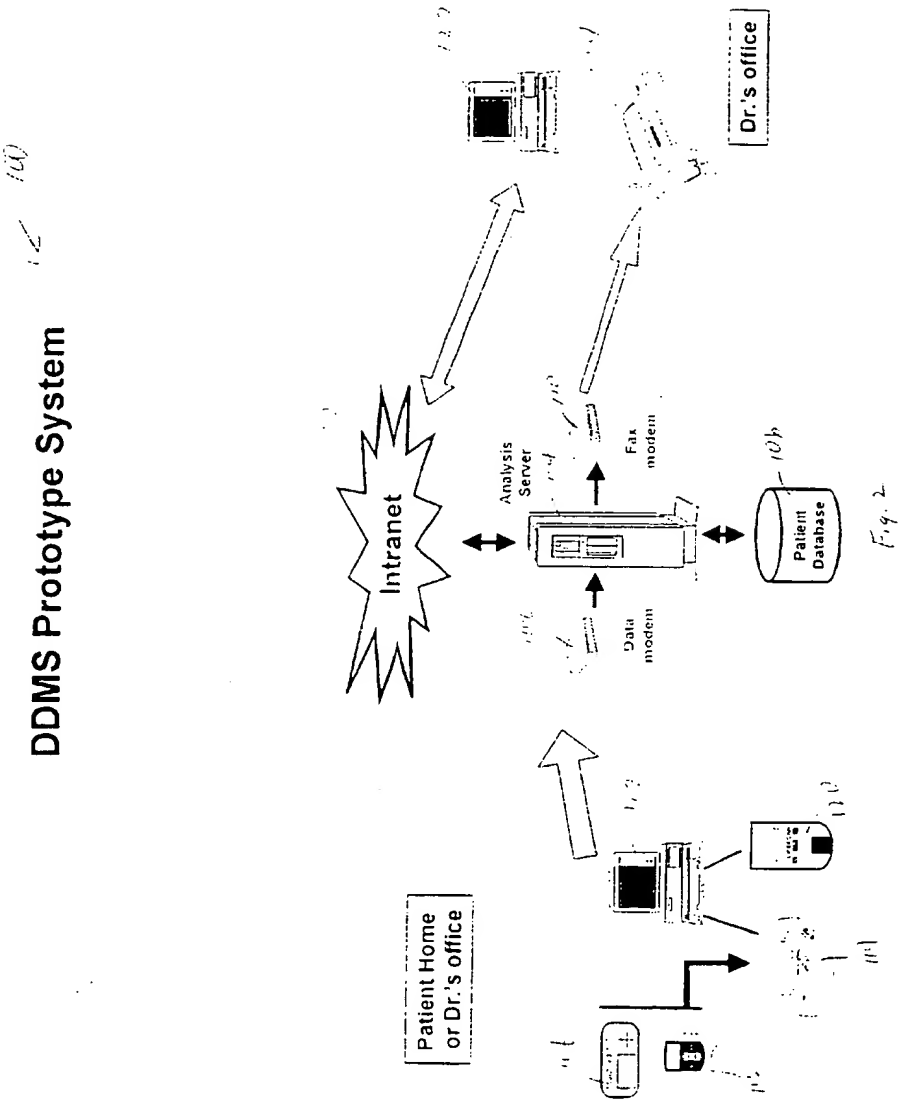
62. The system according to claim 55, wherein the system allows calculations on data combined from the different medical devices to be organized as different groups to be performed in a single operation.

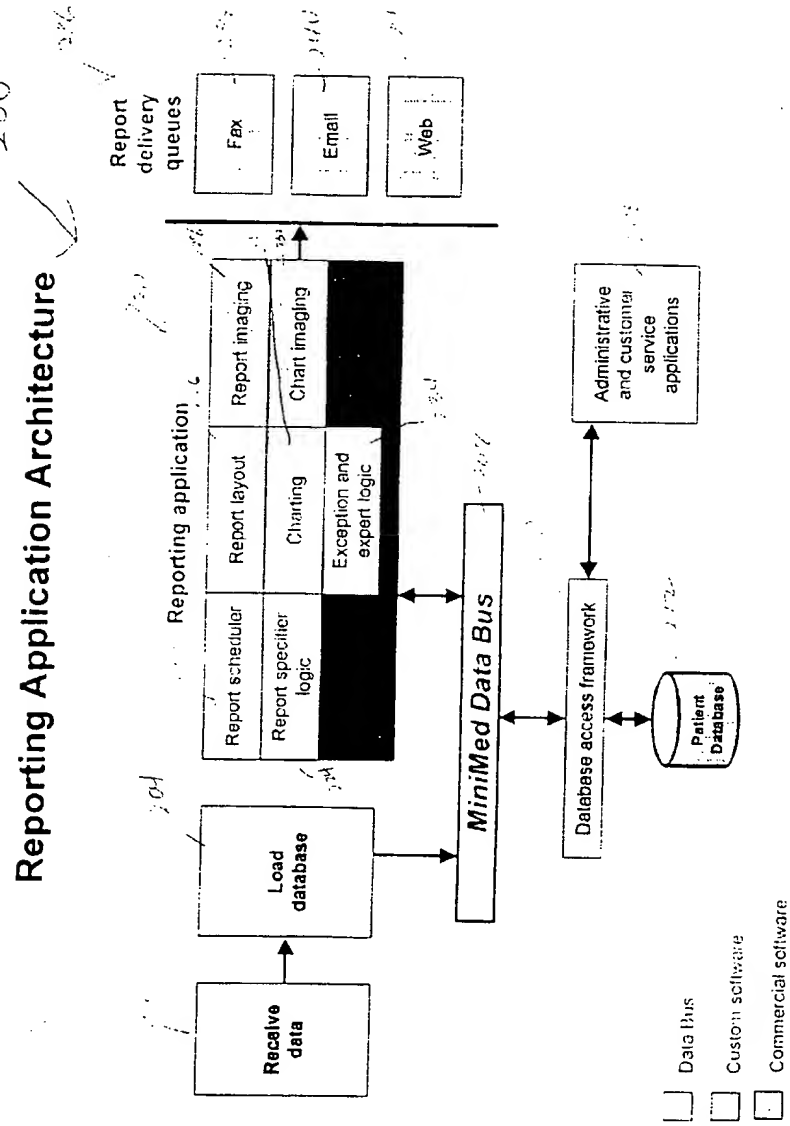
63. The system according to claim 62, wherein the system computes an average blood glucose value as measured by several different blood glucose meters, for each day in a series of days with a single operation.

64. The system according to claim 55, wherein the system allows data from new different medical devices to be combined into the system with minimal of additional programming.

65. The system according to claim 55, wherein the system allows data from different medical devices with similar purposes having data in various different data formats and types to be combined on a single, uniform report or graph.


DDMS Network System
Internet
Public Network
Web Server
Analysis Server
Fax modems
Data modems
Patient Database
MCO
Dr.'s office
Patient Home
Patient Home or Dr.'s office
Not shown
Administrative applications
Firewalls
Email delivery


DDMS Prototype System
Dr.'s office
Intranet
Analysis Server
Fax modem
Data modem
Patient Database
Patient Home or Dr.'s office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Report delivery queues
Fax
Email
Web
Reporting application
Report imaging
Chart imaging
Report layout
Charting
Exception and expert logic
Report scheduler
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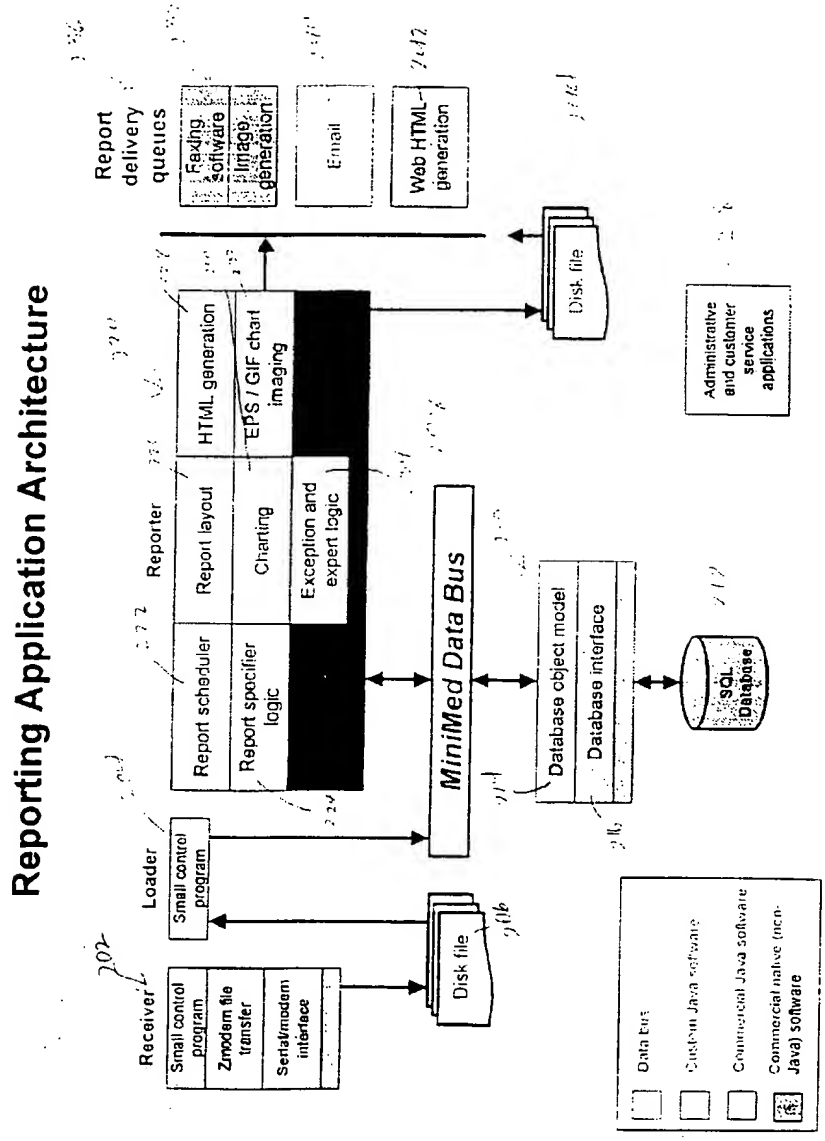
Receive data
MiniMed Data Bus
Database access framework
Administrative and customer service applications
Patient Database
Data flow
Custom software
Commercial software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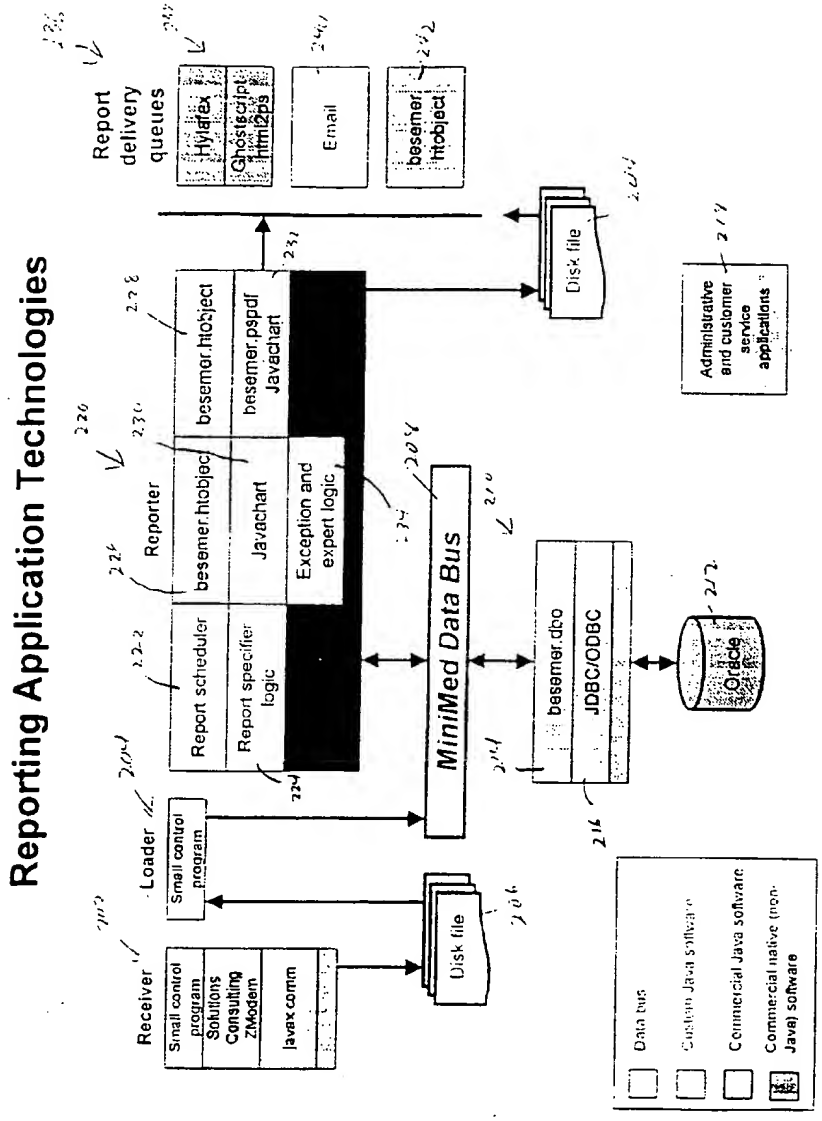
Small control program
Zmodem file transfer
Serial/modem interface
Loader
Small control program
Disk file
MiniMed Data Bus
Reporter
Report scheduler
Report specifier logic
Report layout
Charting
Exception and expert logic
HTML generation
EPS / GIF chart imaging
Report delivery queues
Faxing software
Image generation
Email
Web HTML-generation
Disk file
Database object model
Database interface
SQL Database
Administrative and customer service applications
Data Bus
Custom Java software
Commercial Java software
Commercial native (non-Java) software

Fig 4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Report delivery queues
Hylafax
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besemer.htobject
besemer.pspdf Javachart
Loader
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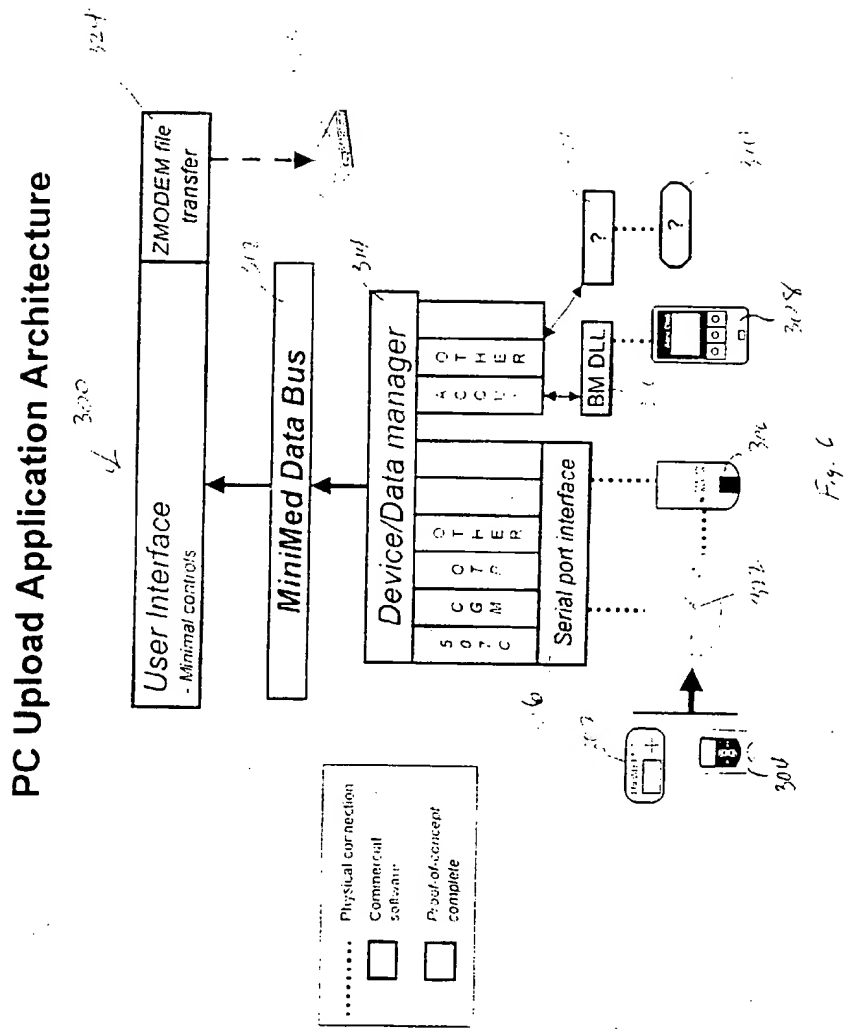
Receiver
Small control program
Solutions Consulting ZModem
Javax comm
Disk file
Disk file
MiniMed Data Bus
besemer.dbo
JDBC/ODBC
Oracle
Administrative and customer service applications
Data bus
Custom Java software
Commercial Java software
Commercial native (non-Java) software

Fig. 5


PC Upload Application Architecture
User Interface
- Minimal controls
ZMODEM file transfer
MiniMed Data Bus
Device/Data manager
SOFTCOMM
OTHER
OTHER
Serial port interface
BM DLL
?
?
Physical connection
Commercial software
Proof of concept complete

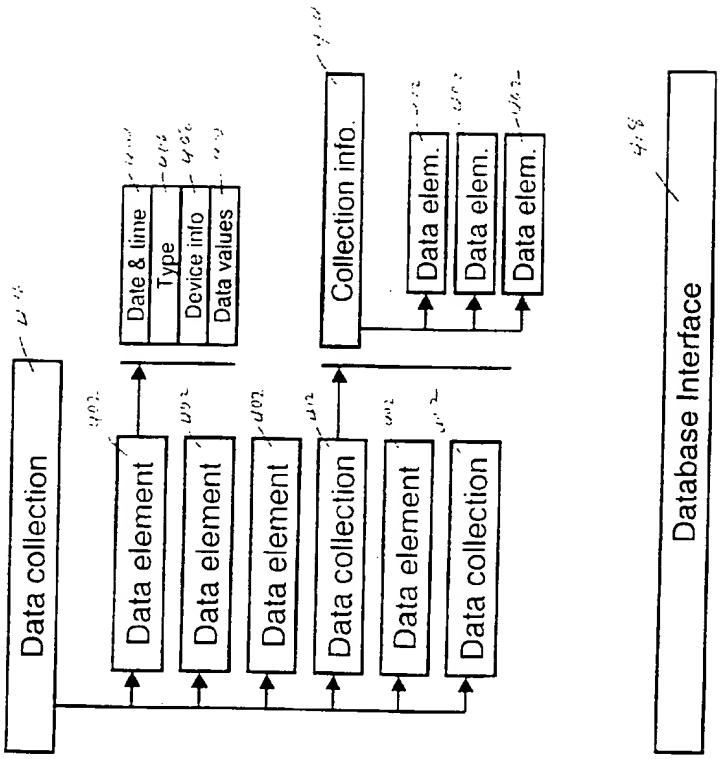

MiniMed Data Bus
Data collection
Data element
Data element
Data element
Data collection
Data element
Data collection
Date & time
Type
Device info
Data values
Collection info.
Data elem.
Data elem.
Data elem.
Database Interface

Fig. 7

Programs:	Device data management	Practice data management	Quality & standards of care	Disease state management
Characteristics of data/systems	Blood glucose and insulin reports	Labs and exam data	DQIP, ADA, etc. parameters	Identify and support interventions with high risk patients

Fig. 8

MiniMed Interactive Reporting Tool

MiniMed Analytical Products

Interactive Reporting Tool

Patient: Doe, Jonn - 123456789

Report: GlucoseInsulinSummary

Report date: January : 1999

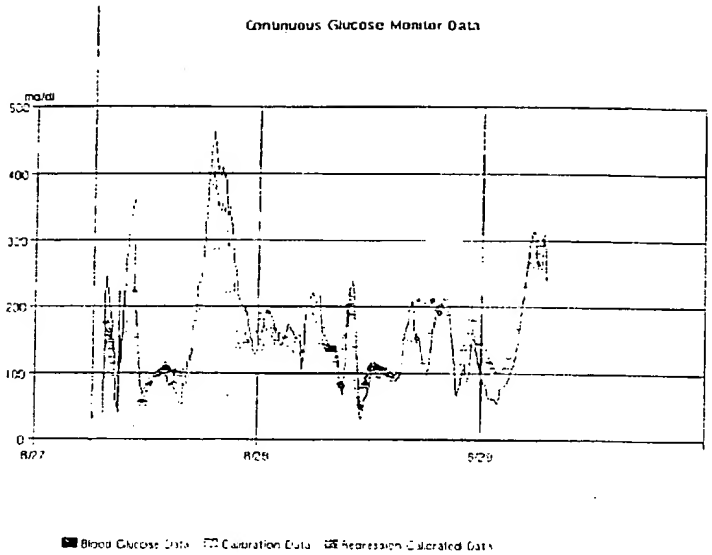
Create Report Reset

Session ID: 927229579198

Page Name: Main

Fig. 9

Subject: John Doe: null CGM Summary Report



Day	Average BG	High index	Low index	% 180	< 70	Pairs	Slope	Offset	Mean Err.	Corr. Coef.	Code
Overall	158.8	5,174.4	209.6	34%	11%						
08/27/1998	182.7	11,590.7	505.3	46%	16%	92	7.2	-3.0	25.0%	0.76	5
08/28/1998	140.6	442.6	37.8	24%	5%	138	7.8	-3.0	12.0%	0.93	0
08/29/1998	159.9	4,977.2	39.6	41%	20%	26	7.3	-3.0	22.0%	0.94	0

Fig. 10

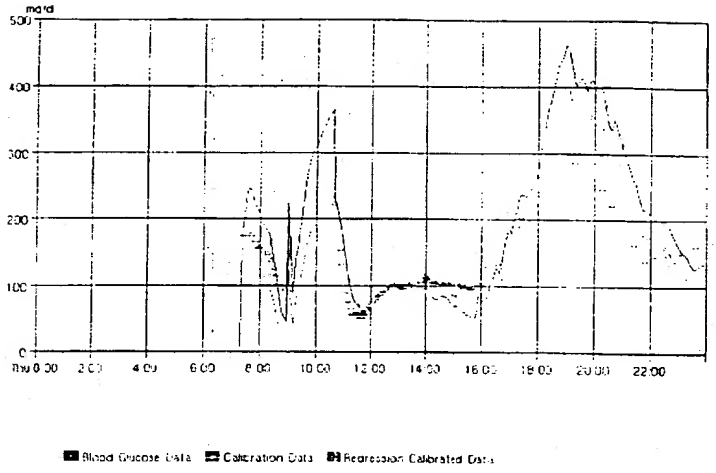

CGM graph for day # 1 (08/27/1998)
mg/dl
500
400
300
200
100
0
Thu 0:00
2:00
4:00
6:00
8:00
10:00
12:00
14:00
16:00
18:00
20:00
22:00
Blood Glucose Data
Calibration Data
Regression Calibrated Data

Fig. 11

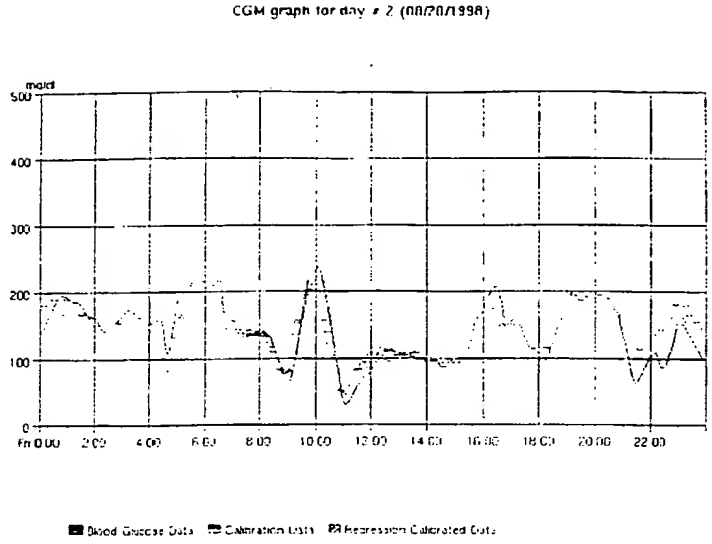

CGM graph for day # 2 (08/20/1998)
mg/dl
500
400
300
200
100
0
6h 0.00
2 00
4 00
6 00
8 00
10 00
12 00
14 00
16 00
18 00
20 00
22 00
Blood Glucose Data
Calibration Data
Regression Calibrated Data

Fig. 12

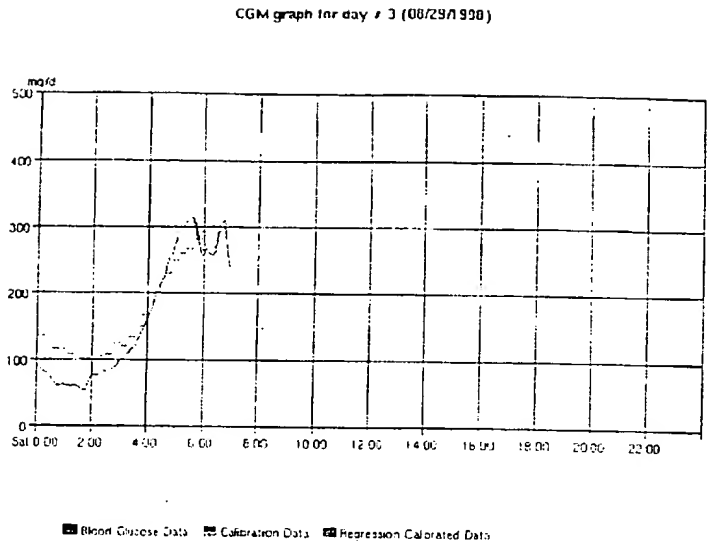

CGM graph for day # 3 (08/29/1998)
mg/d
500
400
300
200
100
0
Sat 0:00
2:00
4:00
6:00
8:00
10:00
12:00
14:00
16:00
18:00
20:00
22:00
Blood Glucose Data
Calibration Data
Regression Calibrated Data

Fig. 13

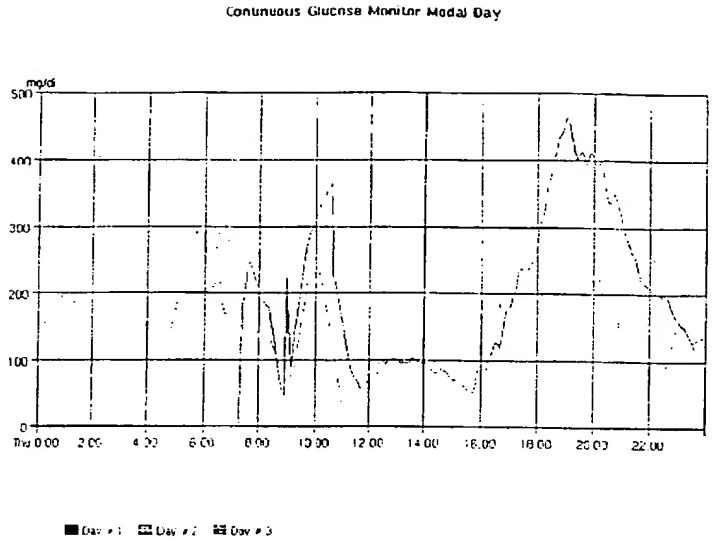
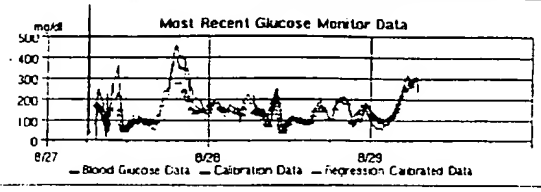
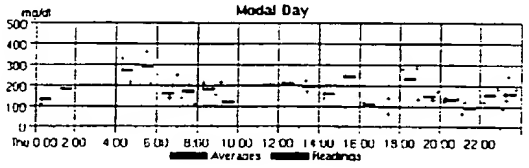

Continuous Glucose Monitor Modal Day
mg/dl
500
400
300
200
100
0
Thu 0:00
2:00
4:00
6:00
8:00
10:00
12:00
14:00
16:00
18:00
20:00
22:00
Day # 1
Day # 2
Day # 3

Fig. 14

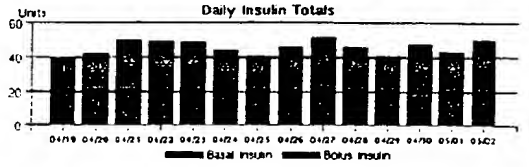
Patient: John Doe Two Week Summary Report: 04/19/1999 - 05/03/1999





Blood Glucose Summary Statistics:

Blood glucose target range	80-140 mg/dl	Blood glucose values within target:	40%
Average blood glucose	167 mg/dl	Blood glucose values below target	6%
Average blood glucose readings/day	3.6	Blood glucose values above target	54%



Insulin Summary Statistics (daily averages):

Bolus count:	9.1	Total insulin	45.9 units
		Bolus insulin:	25.1 units (55%)
		Basal insulin	20.8 units (45%)

Fig. 15